



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
New England District

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One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 279-1675  
FAX: (781) 279-1742

**WARNING LETTER**

**NWE-30-01W**

VIA FEDERAL EXPRESS

June 28, 2001

Will Wang  
President  
Sushi Sushi Inc.  
1212 Broadway  
Somerville, MA 02143

Dear Mr. Wang:

We inspected your firm, located at 1212 Broadway, Somerville, MA, on June 12 and 13, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention during previous inspections, cause your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

- You must implement the monitoring procedure listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did record any temperatures at the receiving critical control point, (CCP) to control the pathogen hazard listed in your HACCP plan for salmon. During the inspection there were no records to demonstrate that this temperature is being recorded as required by your HACCP plan. Also, your HACCP plan for tuna states that the freezer temperature be recorded twice daily. During the inspection it was noted that two of your three freezers do not contain freezer thermometers.

- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not maintain any sanitation records since 9/12/001, to demonstrate that the processing area was clean before processing. During the inspection, food debris was noted on and around the cookers and stoves in your hot food processing room.

We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your modified HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 1708.

Sincerely,



Gail T. Costello  
District Director  
New England District Office